UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,580	10/06/2003	Usha Kasid	224378	8237

23460 7590 04/20/2006

LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6780

EXAMINER	
HUMPHREY, DAVID HAROLD	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/679,580	KASID ET AL.	
	Examiner	Art Unit	
	David Humphrey	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to an isolated nucleic acid molecule, a vector, and a host cell, classified in class 536, subclass 23.1, for example.

II. Claims 12-18, drawn to an isolated polypeptide and an epitope-bearing portion comprising an amino acid sequence consisting essentially of SEQ ID NO: 2, classified in class 530, subclass 350.

III. Claims 19 and 20, drawn to an antibody that binds to SEQ ID NO: 2, classified in class 424, subclass 130.1.

IV. Claims 21 and 22, drawn to a method of increasing survival or proliferation of a cell by inhibiting the expression of SCC-112 using an antisense oligonucleotide, classified in class 536, subclass 24.5.

V. Claims 23 and 24, drawn to an antisense oligonucleotide that inhibits the expression of SCC-112, classified in class 536, subclass 24.5.

VI. Claim 25, drawn to a method of treating disease cells characterized by SCC-112 overexpression comprising administering an antisense oligonucleotide, classified in class 435, subclass 375. Claim 25 will be examined with the instant group to the extent that an antisense oligonucleotide is administered.

VII. Claim 25, drawn to a method of treating disease cells characterized by SCC-112 overexpression comprising administering a ribozyme,

classified in class 435, subclass 91.31. Claim 25 will be examined with the instant group to the extent that a ribozyme is administered.

VIII. Claim 25, drawn to a method of treating disease cells characterized by SCC-112 overexpression comprising administering a small molecule, classified in class 552, subclass 1, for example. Claim 25 will be examined with the instant group to the extent that a small molecule is administered.

IX. Claim 25, drawn to a method of treating disease cells characterized by SCC-112 overexpression comprising administering a small interfering RNA, classified in class 536, subclass 24.5. Claim 25 will be examined with the instant group to the extent that a small interfering RNA is administered.

X. Claim 26, drawn to a method of treating disease cells characterized by SCC-112 overexpression by administration of an antibody that binds to SCC-112 protein of about 150 kDa, classified in class 424, subclass 139.1. Claim 26 will be examined with the instant group to the extent that an antibody that binds a 150 kDa SCC-112 protein is administered.

XI. Claim 26, drawn to a method of treating disease cells characterized by SCC-112 overexpression by administration of an antibody that binds to a mutant SCC-112 protein of about 65 kDa, classified in class 424, subclass 130.1. Claim 26 will be examined with the

instant group to the extent that an antibody that binds a 65 kDa SCC-112 protein is administered.

XII. Claim 27 and 28, drawn to a method of detecting cancer characterized by SCC-112 mRNA underexpression comprising detecting the levels of SCC-112 mRNA expression, classified in class 435, subclass 7.23.

XIII. Claims 29 and 30, drawn to a method of detecting cancer characterized by SCC-112 underexpression comprising detecting the levels of SCC-112 of about 150 kDa using an antibody, classified in class 435, subclass 7.1. Claims 29 and 30 will be examined with the instant group to the extent that an antibody that detects SCC-112 of 150 kDa is utilized.

XIV. Claims 29 and 30, drawn to a method of detecting cancer characterized by SCC-112 underexpression comprising detecting the levels of SCC-112 of about 65 kDa using an antibody, classified in class 424, subclass 139.1. Claims 29 and 30 will be examined with the instant group to the extent that an antibody that detects SCC-112 of 65 kDa is utilized.

XV. Claims 31, 33, 34, 35, 36, 38, 39, and 40, drawn to a method of inducing apoptosis or treating cancer cells or a degenerative disease comprising administering SCC-112 cDNA that enhances SCC-112 expression, classified in class 514, subclass 44. Claims

33, 34, 35, 38, 39, and 40, will be examined with the instant group to the extent that an SCC-112 cDNA is administered that enhances SCC-112 expression.

XVI. Claims 32, 33, 34, 35, 37, 38, 39, and 40, drawn to a method of inducing apoptosis or treating cancer cells or a degenerative disease comprising administering SCC-112 protein or SCC-112 peptide, classified in class 424, subclass 277.1. Claims 33, 34, 35, 38, 39, and 40, will be examined with the instant group to the extent that an SCC-112 protein is administered.

XVII. Claim 40, drawn to a method for treating a patient suffering from a degenerative disease or disorder by administering an agent that enhances the expression of the SCC-112 gene, classified in class 435, subclass 464. Claim 40 will be examined with the instant group to the extent that an agent is administered that enhances the expression of SCC-112 gene.

XVIII. Claim 40, drawn to a method for treating a patient suffering from a degenerative disease or disorder by administering an agent that enhances the production of the SCC-112 protein, classified in class 435, subclass 375. Claim 40 will be examined with the instant group to the extent that an agent is administered that enhances the production of SCC-112 protein.

XIX. Claim 41, drawn to an antibody generated against the polypeptide having an amino acid sequence of SEQ ID NO: 3, classified in class 424, subclass 138.1.

2. The inventions are distinct, each from the other because of the following reasons:

The products of Inventions I-III, V, and XIX, are patentably distinct. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P § 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products constitute patentably distinct inventions. Inventions I-III, V, and XXI, are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The nucleic acids of Invention I, are separate and distinct form the polypeptides of Inventions II, the antibodies of Inventions III and XXI, and the antisense oligonucleotides of Invention V. For example, proteins and nucleic acids have substantially different physical, chemical, structural and functional properties. Moreover, they are made using different techniques and reagents and have materially different modes of operation in vivo. DNA, deoxyribonucleic acids are unbranched polymers composed of four subunits whereas polypeptides of Groups are a linear order of amino acid residues. The antibodies are separate and distinct from the polypeptides because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a

pharmaceutical composition or in assays for the identification of agonists or antagonists of the protein.

The antibodies of Inventions III and XIX are separate and distinct because they recognize patentably distinct amino acid sequences. Invention III is raised against the polypeptide of SEQ ID NO: 2 whereas the antibody of Invention XIX is raised against the antibody of SEQ ID NO: 3.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons. The methods of Inventions IV, VI-XVIII have different method objectives, methods steps and parameters, and utilize different reagents. For example, Invention IV is a method of increasing survival of a cell using an antisense oligonucleotide to SCC-112. Inventions VI-XI dranw to method of treating disease cells are patentably distinct because they utilize patentably distinct reagents. For example, Invention VI comprises administering an antisense oligonucleotide, whereas Inventions VII, VIII, IX, X, XI, comprise administering a ribozyme, a small molecule, siRNA, antibody that binds to 150 kDa SCC-112, and an antibody that binds a mutant SCC-112, respectively. These reagents have patentably distinct chemical structures and functions, and have materially different modes of operation in vivo. Inventions XII-XIV are drawn to methods of detecting cancer, however they utilize separate and distinct reagents and determine the levels of

SCC-112 using mRNA, an antibody that binds to 150 kDa isoform of SCC-112, and an antibody that binds a mutant of SCC-112 respectively.

Inventions XV and XVI are drawn to methods of inducing apoptosis or treating cancer by administering patentably distinct reagents, cDNA and protein, respectively. Finally, Inventions XVII and XVIII utilize patentably distinct reagents in a method of treating patients suffering from a degenerative disease. Invention XVII requires the administration of an agent that enhances the expression of the SCC-112 gene while Invention XVIII requires an agent that enhances the production of the SCC-112 protein.

Inventions I and XV, II and XVI, III and X, III and XIII, V and IV, V and VI, XIX and XI, XIX and XIV, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids of Group I can also be used for hybridization assays. Furthermore, the polypeptide of Invention II can be used to screen for potential binding partners, the antibodies of Inventions III and XIX can be used to purify the target antigens, and the antisense molecule of Invention V can be used in hybridization assays.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. If Applicants elect Invention XV, XVI, XVII, or XVIII, Applicants are further required to elect a species. This application contains claims directed to the following patentably distinct species of the claimed invention: claim 40 recites methods directed to treating patients suffering from the following degenerative diseases or disorders

a. global ischemic stroke;

b. focal ischemic stroke;

c. head trauma;

d. spinal cord injury;

e. hypoxia-induced nerve cell damage;

f. nerve cell damage caused by cardiac arrest;

g. nerve cell damage caused by neonatal distress;

h. epilepsy;

i. anxiety;

j. diabetes mellitus;

k. multiple sclerosis;

l. phantom limb pain;

m. causalgia;

n. neuralgias;

o. herpes zoster;

p. spinal cord lesions;

q. hyper algesia;

r. allodynia;

s. Alzheimer's Disease;

t. Huntington's disease;

u. Parkinson's disease;

v. multiple sclerosis; and

w. amyotrophic lateral sclerosis.

The degenerative diseases and disorders listed above constitute patentably distinct species since the diseases have different etiological origins, treatment protocols, and symptoms.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Humphrey whose telephone number is (571) 272-5544. The examiner can normally be reached on Mon-Fri 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

David Humphrey, Ph.D.

April 12, 2006